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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,888	08/27/1998	AGNETA PETTERSSON	1103326-0519	8291

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WHITE & CASE LLP  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/125,888

Applicant(s)

PETTERSSON ET AL.

Examiner

MONZER R CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This final office action is in response to the amendment received on 07/18/2002

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (U.S.P.N. 3,442,686) in view of Gordon et al (U.S.P.N. 3,967,728).

With respect to claim 1; Jones discloses a method (examples 1-16) of using a laminate as a barrier material against gases (col.2, lines 4-7), the method includes forming the laminate (col.5, lines 45-63) having an inner polypropylene layer (col.4, line 20), an outer polyethylene terephthalate layer (col.4, lines 60-62 and col.8, lines 20-21), and an intermediate silicon oxide layer (col.1, lines 17-19). In addition, Jones's laminate acts as a barrier when exposed to gases in general (col.1, lines 25-27). However, with respect to claim 1, Jones fails to explicitly teach the specific type of gas such as ethylene oxide. Since Jones's laminate is in the art of packaging, it intrinsically includes materials to be sterilized are packaged and ethylene oxide is a well-known gas sterilant. Gordon et al, which is in the art of packaging catheters discloses that packages to be gas sterilized need to be impermeable to sterilizing gases such as ethylene oxide (col.3, lines 45-48). Thus, it would have been obvious and one having ordinary skill in the art would have been motivated to utilize the teachings of Jones to Gordon et al so that any deleterious effects of ethylene oxide (Gordon et al, col.3, lines 46-48) are prevented by using an intermediate layer of silicon oxide which is known to possess superior barrier properties (Jones, col.4, lines 35-37).

With respect to claims 2-5; Jones teaches the following: the polyolefin is polypropylene (col.4, line 20); the polyester for the outer layer of the laminate is polyethylene terephthalate (col.4, lines 60-62 and col.8, lines 20-21); the polyamide is nylon (col.4, line 26); and the silicon oxide containing intermediate layer is a layer of

silicon oxide deposited in-between the facing surfaces of the inner and outer layers (figure 1, intermediate layer).

With respect to claims 6-10; Jones discloses an intermediate layer, which includes a layer of silicon and a polymeric matrix (col.2, lines 30-36, lines 55-59, col.4, lines 13-18, and col.6, lines 31-34). Furthermore, since all the various types of polymers in claims 7-9 have been shown to be disclosed as indicated above, the choice of such types in the construction of the matrix is well within the scope of a person having an ordinary skill in the art of designing laminates.

### ***Response to Arguments***

6. Applicant's arguments filed 07/18/2002 have been fully considered but they are not persuasive.

On page 2 of the response; applicant argues that Jones does not disclose or suggest the use of the laminate as a barrier material against ethylene oxide gas. However, Jones teaches that the laminate is to be used for packaging (col.1, line 13). Thus, it would have been obvious to use the packaging material of Jones during ethylene oxide sterilization of Gordon. The Gordon reference only used to show ethylene oxide gas sterilization.

On page 3 of the response; applicant argues that Jones teaches that the barrier layer can only be metal or aluminum foil. Jones does not limit the barrier layer to metal or aluminum foil. See figure 6, where the barrier layer is made up of Mylar (polyester).

On pages 3 and 4 of the response; applicant argues, "the examiner is relying on an improper standard of obviousness without a reasonable expectation of success".

However, it is not obvious to try because Jones teaches the instant packaging film as admitted by the applicant to protect objects from permeability from gas or liquid.

On pages 3 and 4 of the response; applicant argues that Gordon should not be combined with Jones. Both references are in the art of designing package material that acts as a barrier against sterilants. Also, Gordon reference only used to show that ethylene oxide sterilization is known.

On page 4 of the response; applicant argues that Gordon teaches that medical packaging materials should be impermeable to sterilizing gases such as ethylene oxide. Jones also teaches the concept of the impermeability to gases as well. Furthermore, Jones teaches the instant packaging film as admitted by the applicant to protect objects from permeability from gas or liquid.

On page 4 of the response; applicant argues that the low permeability membrane of Jones does not necessarily mean that the material can be used as a barrier to sterilizing gases. However, Jones teaches the instant packaging film as admitted by the applicant to protect objects from permeability from gas or liquid.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Christensen et al (U.S.P.N. 5,942,408), Weiss et al (U.S.P.N. 5,653,090), Birchall et al (U.S.P.N. 3,839,078), and Shichman et al (U.S.P.N. 5,322,161) disclose laminates as a barrier material against gases used in the art of gas sterilization.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

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Monzer R. Chorbaji *MRC*  
Patent Examiner  
AU 1744  
October 21, 2002

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